



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0530]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Tropical Disease Priority Review Vouchers.

**DATES:** Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2008-D-0530 for the “Tropical Disease Priority Review Vouchers.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Tropical Disease Priority Review Vouchers

OMB Control Number 0910-0822--Revision

Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section 524 of the FD&C Act, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524 of the FD&C Act, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act).

Accordingly, we have developed the guidance document entitled, "Guidance for Industry (GFI): Tropical Disease Priority Review Vouchers." The guidance explains how FDA will

implement the provisions of section 524 of the FD&C Act, how sponsors may use priority review vouchers, and how priority review vouchers may be transferred to other sponsors. The guidance also explains eligibility criteria for tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act, and provides instructions to sponsors on how they may:

- request a priority review voucher; and
- notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application.

The guidance also explains that transfer of a priority review voucher from one sponsor to another is permitted and that each transfer should be documented with a letter of transfer. Finally, the guidance will be revised to include new information collection established by section 611 of the FDA Reauthorization Act of 2017 (FDARA). As amended, section 524 of the FD&C Act requires the sponsor of a tropical disease product application to include an attestation regarding its eligibility for a priority review voucher.

*Description of Respondents:* Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

We estimate the burden of the information collection as follows:

Table 1--Estimated Annual Reporting Burden<sup>1</sup>

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent to Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Attestation of Eligibility	5	1	5	2	10
Total					122

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

We have increased our burden estimate since last approval to account for attestations added by FDARA; however, all other information collection elements remain unchanged.

Dated: November 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-24320 Filed: 11/6/2018 8:45 am; Publication Date: 11/7/2018]